# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

24 Jun 2026

## The effect of Cupping on nonspecific lumbar pain of the elderly referred to the Iranian Medicine Clinic.

### Protocol summary

**Study aim**

Determining the effect of Cupping on nonspecific lumbar pain of the elderly referred to the Iranian Medicine Clinic of Kerman University of Medical Sciences

**Design**

This clinical trial was designed with 70 patients in two groups of cupping therapy and placebo by a simple random method for 10 days, into every other day in even or odds day to avoid patients of two groups confronting each other. the patients record their probably complications and pain intensity based on vas questionnaire from 0-10 in checklist.

**Settings and conduct**

This study is designed for elderly patients with non-specific low back pain in Kerman traditional Persian medicine clinic.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Willingness and satisfaction of the patient to participate in the study The presence of non-specific musculoskeletal pain in the lower back based on the doctors diagnosis Age>60 years (35) Mild to moderate pain intensity 4-8 on VAS Low back pain>=3 month (8) BMI <35 (34) Exclusion criteria: Back pain caused by trauma inflammatory or malignant disease Presence of coagulopathy disease or anticoagulant agent consumption Existence of radiculopathy symptoms such as radiating pain, paresis, prickling, or tingling of lower limb Serious acute or chronic organic disease such as diabetes, mental disorders Congenital malformation of the spine Treatment with physiotherapy or opiates and other procedures within the last 4 weeks Central Nervous System impairment

**Intervention groups**

This study is an interventional research as a clinical trial. The first group is undergoing cupping therapy and the second group received placebo with slight negative pressure and Double-sided adhesive.

**Main outcome variables**

pain intensity VAS Questionnaire (0-10)

### General information

**Reason for update**

**Acronym**

CT

**IRCT registration information**

IRCT registration number: **IRCT20200720048152N1**
Registration date: **2023-02-01, 1401/11/12**
Registration timing: **retrospective**

Last update: **2023-02-01, 1401/11/12**
Update count: **0**

**Registration date**

2023-02-01, 1401/11/12

**Registrant information**

**Name**

Zohreh Sarhadinejad

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 34 4425 2922

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-12-13, 1401/09/22

**Expected recruitment end date**

2023-01-25, 1401/11/05

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
The effect of Cupping on nonspecific lumbar pain of the elderly referred to the Iranian Medicine Clinic.

**Public title**
The effect of Cupping on lumbar pain of the elderly

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Willingness and satisfaction of the patient to participate in the study The presence of non-specific musculoskeletal pain in the lower back based on the doctors diagnosis Age>60 years (35) Mild to moderate pain intensity 4-8 on VAS Low back pain>=3 month (8) BMI <35 (34)

**Exclusion criteria:**
Back pain caused by trauma inflammatory or malignant disease Presence of coagulopathy disease or anticoagulant agent consumption Existence of radiculopathy symptoms such as radiating pain, paresis, prickling, or tingling of lower limb Serious acute or chronic organic disease such as diabetes , mental disorders Congenital malformation of the spine Treatment with physiotherapy or opiates and other procedures within the last 4 weeks Central Nervous System impairment

**Age**
From **60 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **70**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Randomization is done in a simple way using a table of random numbers. The collaborator of the Project, who does not intervene in the research process, first prepares pockets according to sample size and numbers them, then based on the table of random numbers, randomly select a number and read the entire column bellow it vertically. The numbers whose right two digits are between 01 to 70 up to 35 numbers are placed in cupping therapy group and the rest are assigned to the placebo group. The type of treatment is written in each envelope and envelopes are closed and sealed. A four-digit code is written on each envelope. Two digits on the left correspond to the order of patient's entry into the study and completes the informed consent form, are added to the first digits. an envelope is opened and the assigned group and day of visit is specified for that patient.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
In order to blind the study, The collaborator of the project, who was not involved in the treatment process or the data analysis process, puts the patients into two groups by a simple random method and using a sealed envelope. The first group is treated with dried cupping, and the second group is treated with placebo (cupping glasses are placed on the skin with a slight negative pressure and use of glue).

**Placebo**
Used

**Assignment**
Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Research Ethics Committees of Kerman University of Medical Sciences

**Street address**
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

**City**
Kerman

**Province**
Kerman

**Postal code**
7616913555

**Approval date**
2022-12-12, 1401/09/21

**Ethics committee reference number**
IR.KMU.REC.1401.389

## Health conditions studied

### 1

**Description of health condition studied**
low back pain

**ICD-10 code**
M54.5

**ICD-10 code description**
کمردرد

## Primary outcomes

### 1

**Description**
low back pain intensity

**Timepoint**
registration of daily pain intensity from day 0-10

**Method of measurement**

Visual Analog Scale questionnaire: VAS (0-10)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: After random allocation of patients in to two groups of cupping therapy and placebo, in cupping therapy group, 4-10 acrylic cups with a diameter of 25-50 mm were used, the air inside them was heated by the flame of alcohol cotton and the cups were placed on paravertebral region at a distance between l1 and l5 in parallel, for 7-10 minutes. As the air inside the cup cools down and creates suction, the skin is drawn into the cup due to the created vacuum. In such a way that the skin turns from bright red to dark pink. The duration of treatment is 10 days, into every other day in even or odds day to avoid patients of two groups confronting each other. Generally, each person is subjected to 5 sessions. If analgesics are needed, matching is done in both groups.

**Category**

Treatment - Devices

### 2

**Description**

Control group: In the placebo group, by a manual cupping machine with a single suction and double adhesive support, 4-10 acrylic cups with a diameter of 25-50 mm, are attached only to the suction position on both sides of the vertebral column and in parallel at a distance between l1 and l5 (without changing the color of the skin). The cups are removed after 7-10 minutes. The duration of treatment is 10 days, into every other day in even or odds day to avoid patients of two groups confronting each other. Generally, each person is subjected to 5 sessions. If analgesics are needed, matching is done in both groups.

**Category**

Treatment - Devices

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Traditional Medicine clinic

**Full name of responsible person**
Ali Sarhadinejad

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No. 1,Emam Jome Ave, Kerman

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Kerman University of Medical Sciences

**Full name of responsible person**
Research assistant

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
No

**Title of funding source**
with out grant

**Proportion provided by this source**
1

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Kerman University of Medical Sciences

**Full name of responsible person**
Ali Sarhadinejad

**Position**
student

**Latest degree**
Bachelor

**Other areas of specialty/work**

Nursery
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available